TABLE 3-continued

Formula of Oxycodone HCl 10 mg Controlled Release Tablets

Component	Mg/Tablet	Percent (by wt)
Purified Water	q.s.*	—
Stearyl Alcohol	25.00	20
Talc	2.50	2
Magnesium stearate	1.25	1
Total:	125.00 mg	100

*Used only in the manufacture and remains in final product as residual quantity only.

The tablets of Example 2 are then tested for dissolution via USP Basket Method at 37° C., 100 RPM, first hour 700 ml simulated gastric (pH 1.2) then changed to 900 ml at pH 7.5. The results are set forth in Table 4 below:

TABLE 4

Dissolution of Oxycodone 10 mg Controlled Release Tablets

Hour	% Dissolved
1	35.9
2	47.7
4	58.5
8	67.7
12	74.5
18	76.9
24	81.2

EXAMPLE 3

Controlled Release Oxycodone 10 mg Tablets (Aqueous Manufacture)

Eudragit ® RS 30D and Triacetin ® are combined while passing though a 60 mesh screen, and mixed under low shear for approximately 5 minutes or until a uniform dispersion is observed.

Next, suitable quantities of Oxycodone HCl, lactose, and povidone are placed into a fluid bed granulator/dryer (FBD) bowl, and the suspension sprayed onto the powder in the fluid bed. After spraying, the granulation is passed through a #12 screen if necessary to reduce lumps. The dry granulation is placed in a mixer.

In the meantime, the required amount of stearyl alcohol is melted at a temperature of approximately 70° C. The melted stearyl alcohol is incorporated into the granulation while mixing. The waxed granulation is transferred to a fluid bed granulator/dryer or trays and allowed to cool to room temperature or below. The cooled granulation is then passed through a #12 screen. Thereafter, the waxed granulation is placed in a mixer/blender and lubricated with the required amounts of talc and magnesium stearate for approximately 3 minutes, and then the granulate is compressed into 125 mg tablets on a suitable tabletting machine.

The formula for the tablets of Example is set forth in Table 5 below:

TABLE 5

Formula of Controlled Release Oxycodone 10 mg Tablets

Component	Mg/Tablet	percent (by wt)
Oxycodone Hydrochloride	10.0	8.0
Lactose (spray dried)	69.25	55.4
Povidone	5.0	4.0
Eudragit ® RS 30D (solids)	10.0*	8.0
Triacetin ®	2.0	1.6
Stearyl Alcohol	25.0	20.0
Talc	2.5	2.0
Magnesium Stearate	1.25	1.0

TABLE 5-continued

Formula of Controlled Release Oxycodone 10 mg Tablets

Component	Mg/Tablet	percent (by wt)
Total:	125.0	100.0

*Approximately 33.33 mg Eudragit ® RS 30D Aqueous dispersion is equivalent to 10 mg of Eudragit ® RS 30D dry substance.

The tablets of Example 3 are then tested for dissolution via the USP Basket Method at 37° C., 100 RPM, first hour 700ml simulated gastric fluid at pH 1.2, then changed to 900ml at pH 7.5.

TABLE 6

Dissolution of Oxycodone 10 mg Controlled Release Tablets

Hour	% Oxycodone Dissolved
1	38.0
2	47.5
4	62.0
8	79.8
12	91.1
18	94.9
24	98.7

EXAMPLES 4-5

In Example 4, 30 mg controlled release oxycodone hydrochloride tablets are prepared according to the process set forth in Example 1.

In Example 5, 10 mg controlled release oxycodone hydrochloride tablets are prepared according to the process set forth in Example 2.

Thereafter, dissolution studies of the tablets of Examples 4 and 5 are conducted at different pH levels, namely, pH 1.3, 4.56, 6.88 and 7.5.

The results are provided in Tables 7 and 8 below:

TABLE 7

Example 4
Percentage Oxycodone HCl 30 mg Tablets Dissolved Over Time

pH	1	2	4	8	12	18	24
1.3	29.5	43.7	61.8	78.9	91.0	97.0	97.1
4.56	34.4	49.1	66.4	82.0	95.6	99.4	101.1
6.88	33.8	47.1	64.4	81.9	92.8	100.5	105.0
7.5	27.0	38.6	53.5	70.0	81.8	89.7	96.6

TABLE 8

Example 5
Percentage Oxycodone HCl - 10 mg Tablets Dissolved Over Time

pH	1	2	4	8	12	18	24
1.3	25.9	41.5	58.5	73.5	85.3	90.7	94.2
4.56	37.8	44.2	59.4	78.6	88.2	91.2	93.7
6.88	34.7	45.2	60.0	75.5	81.4	90.3	93.9
7.5	33.2	40.1	51.5	66.3	75.2	81.7	86.8

EXAMPLES 6-11

In examples 6-11, 4 mg and 10 mg oxycodone Hcl tablets were prepared according to the formulations and methods set forth in the assignee's U.S. Pat. No. 4,844,909.

In Example 6, oxycodone hydrochloride (10.00 gm) was wet granulated with lactose monohydrate (417.5 gm) and hydroxyethyl cellulose (100.00 gm), and the granules were sieved through a 12 mesh screen. The